

**510(k) Summary**

**1.1 Submitter:** MDS Nordion Tel: 613-592-3400 x2372  
447 March Road Fax: 613-592-2006  
Kanata, Ontario K2K 1X8  
CANADA

**Contact Person:** E. S. Martell, Vice President  
Quality & Regulatory Affairs  
447 March Road  
Kanata, Ontario K2K 1X8  
CANADA

**1.2 Device Manufacturer:** MDS Nordion AB  
Box 1704  
SE-75147 Uppsala  
SWEDEN

**1.3 Device Name:** Helax-TMS Proton Functionality

**1.4 Classification Name:** Medical Charged-Particle Radiation Therapy System  
(892.5050)

**1.5 Common or Usual Name:** Radiation Therapy Treatment Planning System

**1.6 Legally Marketed Predicate Device:**

Helax-TMS v 5.0 (K993766), Helax-TMS v 3.0 (K962892) and Helax-TMS v 2.10  
(K953391),  
Varian Proton Vision 7.0 (K002312)

**1.7 Description of Helax-TMS Proton Functionality:**

Helax TMS is a 3D Radiotherapy Treatment Planning (RTP) system for radiation dose planning of patients undergoing external beam and brachytherapy treatment in the Oncology clinic. Helax-TMS is a 3-D system, using modern algorithms for dose calculations. The user has the option of selecting either a convolution/superposition pencil beam or a Collapsed Cone algorithm for photons, a Gaussian pencil beam model for electrons, and a proton dose calculation. A brachytherapy module is integrated into Helax-TMS for treatment modeling of interstitial and intracavity brachytherapy techniques. The system software is designed to lead the user through a logical flow planning process.

## 1.8 Intended use of Helax-TMS Proton Functionality:

Helax-TMS is a 3D radiotherapy treatment planning system for radiation dose planning, but not treatment, of patients undergoing external beam or brachytherapy treatment in the oncology clinic. The system is designed to lead the user through a logical flow planning process.

Based on quality assured radiation therapy input data Helax-TMS is used to plan radiation treatments with:

- (i) Linear accelerators with X-ray energies from 4 to 50MV and electron energies from 4 to 50 MeV, proton energies from 1 to 275 MeV\* as well as cobalt-60 units. Helax-TMS will plan 3D radiotherapy treatment approaches of combined modality plans, asymmetric and non-coplanar fields; total body irradiation; multi-leaf collimators; motorised and dynamic wedges; customised blocking; compensating filters; and bolus.
- (ii) Brachytherapy units for patients undergoing interstitial or intracavitary treatment in the oncology clinic.

Export capabilities exists as part of Helax-TMS to verify beam and patient data, to provide dose planning results, and to provide on-line information to block-cutting devices and milling machines, multi-leaf collimator control units, and record and verify systems.

\*Note: Underlined sentence added due to new proton algorithm.

## 1.9 Technological Characteristics

The Helax-TMS v 5.1 is a modification of the Helax-TMS v 5.0/v 3.0/v 2.10 Radiation Therapy Treatment Planning System. These modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device. There are no differences between the Helax TMS v 5.1 and Helax-TMS v 5.0/v 3.0/v 2.10 that adversely affect the safety or effectiveness of the device.



SEP 26 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. E.S. Martell  
Vice President, Quality  
and Regulatory Affairs  
MDS Nordion, Inc.  
447 March Road  
KANATA ONTARIO CANADA  
K2K 1X8

Re: K010682  
Trade/Device Name: TMS v.5.1 Proton Functionality  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation  
therapy system  
Regulatory Class: II  
Product Code: 90 MUJ  
Dated: February 27, 2001  
Received: March 7, 2001

Dear Mr. Martell:

This letter corrects our substantially equivalent letter of June 5, 2001 regarding the trade name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

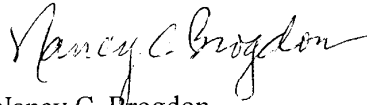
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## 6.0 Indications for Use

510 (k) Number: K010682

Device Name: **Helax-TMS, v.5.1 Proton Functionality**

### Indications For Use:

Helax-TMS is a 3D radiotherapy treatment planning system for radiation dose planning, but not treatment, of patients undergoing external beam or brachytherapy treatment in the oncology clinic. The system is designed to lead the user through a logical flow planning process.

Based on quality assured radiation therapy input data Helax-TMS is used to plan radiation treatments with:

- (i) Linear accelerators with X-ray energies from 4 to 50MV and electron energies from 4 to 50MeV, proton energies from 1 to 275 MeV as well as cobalt-60 units. Helax-TMS will plan 3D radiotherapy treatment approaches of combined modality plans, asymmetric and non-coplanar fields; total body irradiation; multi-leaf collimators; motorised and dynamic wedges; customised blocking; compensating filters; and bolus.
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Export capabilities exists as part of Helax-TMS to verify beam and patient data, dose planning results, and provide on-line information to block-cutting devices and milling machines, multi-leaf collimator control units, as well as record and verify systems.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON  
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(PER 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

David A. Johnson  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

(Optional Format 1-2-96)

510(k) Number K010682